PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

Baldwins
PO Box 5999
Wellesley Street
Auckland
NEW ZEALAND

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* 14 FEB 2005
Applicant's or agent's file reference SH504430/142	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NZ2004/000317	7 December 2004	24 March 2004

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. [7] C07K 1/14 C07K 16/12 C12N 15/11 C12N 15/31

Applicant
AUCKLAND UNISERVICES LIMITED et al

1. This opinion contains indications relating to the following items:

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**DAVID OLDE** Telephone No. (02) 6283 2569

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/NZ2004/000317

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☒ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☒ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☒ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/NZ2004/000317

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims 1-34	YES
	Claims 35	NO
Inventive step (IS)	Claims 1-31	YES
	Claims 32-35	NO
Industrial applicability (IA)	Claims 1-35	YES
	Claims -	NO

2. Citations and explanations:

The invention appears to reside in the finding that SET1 is able to selectively bind with IgA and C5 thus enabling their isolation and/or removal from a sample.

The following documents identified in the International Search report have been considered for the purposes of this report:

D1: Holden, M.T.G. 2004. Proceedings of the National Academy of Sciences (USA). 101(26):9786-9791.

D2: WO 2002 077183 A

D3: WO 2002 094868 A

D4: Arcus, V.L. *et al.* 2002. The Journal of Biological Chemistry. 277(35):32274-32281.

D5: TrEMBLE Accession No: Q8NY48.

D6: Kuroda, M. *et al.* 2001. The Lancet. 357:1225-1240.

D7: Williams, R.J. *et al.* 2000. Infection and Immunity. 68(8):4407-4415.

Novelty (N) and Inventive Step (IS)

D1 was published after the priority date of the present application and is therefore not relevant to the novelty or inventiveness of claims 1-35.

Claims 1-34 are considered novel and inventive in light of D2-D7 as the claimed invention is not disclosed in any of these citations.

Claim 35 lacks novelty in light of each of D2-D7. Each of these citations discloses SET1 or a functional homologue. Due to the use of the word "for" the claim is directed to SET1 *per se* (See Box VIII) . As such the claim lacks novelty as all the essential features are disclosed in each of D2-D7.

Continued in Supplemental Box

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/NZ2004/000317

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 35 is not fully supported by the description with regard to the use of the word "for". Such a phrase places no limitation upon the claims. As such the claims are directed to SET1 or functional equivalents *per se* (as SET1 is well known in the art this claim inherently lacks novelty). Thus as the claim is not limited to SET1 when used in the applicant's method of isolation and/or removal, the scope of the claim is not fully supported.

Claim 35 is not clear as it appears to be incorrectly appended to claim 30.

The claims in general are not fully supported by the description with regard to the phrase "functional equivalents" of SET1. The specification provides the use of alleles of SET1 in methods of isolating IgA or C5. There is no support for the use of any protein having a function equivalent to that of SET1. Furthermore a protein having the function of SET1 in the context of the claims need only be able to bind IgA and/or C5. Thus as the claims are not limited to the use of functional homologues of SET1, the scope of these claims is not fully supported by the description.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International Application No.

PCT/NZ2004/000317

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box V**

Claims 1-31 are considered inventive in light of D2-D7 as the claimed invention is not disclosed or suggested.

Claims 32-35 lack an inventive step in light of each of D2-D7. These claims are directed to allelic variants of SET1. Each of these citations disclose SET1 or functional equivalents. It is clear from each citation that at least each strain of *Staphylococcus aureus* contains variants of SET1 or homologues thereof. As such there is not considered to be any inventive merit in isolating further allelic variants of SET1 or homologues thereof.

Industrial Applicability (IA)

Claims 1-35 meet the requirements of the PCT in regard to industrial applicability.